## Claims:

5

- A method for treatment or prophylaxis of a disease or condition in an animal comprising administering to a mucosal membrane of said animal in need of such treatment a therapeutically effective amount of a drug delivery system comprising at least one physiologically active agent or prodrug thereof and at least one penetration enhancer selected from safe ester sunscreens.
- 10 2. A method according to claim 1 wherein the safe ester sunscreen is present in an amount of from 10 to 10,000 wt% based on the weight of active agent.
- A method according to claim 1 wherein the drug delivery system is
  administered via the oral mucous membrane.
  - 4. A method according to claim 3 wherein the drug delivery system is administered via the buccal or sublingual mucosa.
- A method according to claim 4 wherein said sunscreen ester is of formula I

$$(R^1)_q$$
  $(CH=CH)_n$   $CO_2R^2$ 

wherein

25

R<sup>1</sup> is selected from the group consisting of hydrogen, lower alkyl, lower alkoxy, halide, hydroxy and NR<sup>3</sup>R<sup>4</sup>;

R<sup>2</sup> is a long chain alkyl;

R<sup>3</sup> and R<sup>4</sup> are each independently selected from the group consisting of hydrogen, lower alkyl and the group wherein R<sup>3</sup> and R<sup>4</sup> together with the nitrogen atom to which they are attached form a 5- or 6-membered heterocyclic ring;

30 N is 0 or 1; and q is 1 or 2.

- 6. A method according to claim 5, wherein said ester is selected from the group consisting of a long chain alkyl para-aminobenzoate, long chain alkyl dimethyl-para-aminobenzoate, long chain alkyl cinnamate, long chain alkyl methoxycinnamate and long chain alkyl salicylate.
- 7. A method according to claim 5, wherein said ester is selected from the group consisting of octyl dimethyl-para-aminobenzoate, octyl paramethoxycinnamate and octyl salicylate.

10

5

- 8. A method according to claim 5 wherein the drug delivery system comprises a volatile liquid in an amount to act as a vehicle for the active agent and penetration enhancer.
- 15 9. A method according to claim 8, wherein the volatile liquid is ethanol or isopropanol.
- 10. A method according to claim 8 wherein the dermal penetration enhancer (A) is adapted to transport the physiologically active agent across the mucosal membrane of an animal, when the volatile liquid evaporates to form a reservoir or depot of a mixture comprising the penetration enhancer and the physiologically active agent within said membrane and (B) is of low toxicity to, and is tolerated by, the mucosal membrane of the animal.

- 11. A method according to claim 8, characterised in that after application of the system to an area of the mucosal membrane the volatile liquid evaporates within 10 minutes of application.
- 30 12. A method according to claim 8, characterised in that the volatile liquid evaporates within 3 minutes of application.
  - 13. A drug delivery system according to claim 8, wherein the volatile liquid evaporates within 1 minute of application.

14. A method according to claim 5, wherein the drug delivery system further comprises a component selected from the group consisting of a pharmaceutical compounding agent, co-solvent, surfactant, emulsifier, antioxidant, preservative, stabiliser, diluent and a mixture of two or more of said components.

5

- 15. A method according to claim 1 wherein the drug delivery system further comprises a compounding agent selected from the group consisting of paraffin oils, esters, ethanol, silicone oils and vegetable oils.
  - 16. A method according to claim 5 wherein the compounding agent is present in an amount of from 1 to 80%.
- 15 17. A method according to claim 1 wherein the drug delivery system further comprises a co-solvent selected from the group consisting of ethyl alcohol, isopropyl alcohol, acetone, dimethyl ether and glycol ethers.
- 18. A method according to claim 15 wherein the co-solvent is present in an amount of from 1 to 80%.
  - 19. A method according to claim 1 wherein the drug delivery system comprises a further penetration enhancer selected from the group consisting of laurocapram, derivatives of laurocapram, oleic acid and its ester derivatives, sorbitan esters, fatty acid esters, long chain alkyl esters of 2-pyrrolidone, dodecyl (N,N-dimethylamino) proprionate (DDAIP), 2-n-nonyl-1-3-dioxolane (SEPA®) and sorbitan monooleate.
- 20. A method according to claim 1, wherein the disease or condition is selected from the group consisting of soft tissue injury, narcotic withdrawal, severe post-operative pain, motion sickness, allergic reaction, acne, anxiety disorders, male impotence, sleep disorders, jetlag, herpes virus infections, migraine, high blood pressure, malaria, diagnosis of cystic fibrosis, asthma and nocturnal asthma.

- A method according to claim 5 wherein the physiologically active agent is 21. an antihistamine selected from the group consisting of meclozine, hydroxyzine, brompheniramine, cvclizine. chlorcyclizine, chlorpheniramine, clemastine, cyproheptadine, dexchlorpheniramine, diphenhydramine, diphenylamine, doxylamine, mebhydrolin, pheniramine, tripolidine, azatadine, diphenylpyradine, methdilazine, terfenadine, astemizole, loratadine, cetirizine and pharmaceutically acceptable salts and derivatives of any one of the aforementioned antihistamine agents.
  - 22. A method according to claim 21 wherein the physiologically active agent is loratedine.
- 15 23. A method according to claim 5 wherein the physiologically active agent comprises a benzodiazepine.
- A method according to claim 23 wherein the benzodiazepine is selected from the group consisting of temazepam, doxylamine, triazolam, nitrazepam and pharmaceutically acceptable salts and derivatives of any one of the aforementioned.
  - 25. A method according to claim 5 wherein the physiologically active agent is a cardiovascular agent.

26. A method according to claim 25 wherein the cardiovascular agent is selected from the group consisting of an antihypertensive agent, a calcium channel blocker, an antiarrhythmic agent, an antiangina agent and a beta-adrenergic blocker.

27. A method according to claim 5 wherein the physiologically active agent is a decongestant selected from the group consisting of phenephrine, phenylpropanolamine, pseudoephedrine or pharmaceutically acceptable

30

25

5

salts or derivatives of any one of the aforementioned decongestant agents.

- 28. A method according to claim 5 wherein the physiologically active agent is dextromethorphan.
  - 29. A method according to claim 5 wherein the physiologically active agent is a barbiturate.
- 10 30. A method according to claim 5 wherein the physiologically active agent is a hypoglycaemic agent selected from the group consisting of insulin, chlorpropamide, glibenclamide, gliclazide, glipizide, tolazamide, tolbutamide, metformin or pharmaceutically acceptable salts or derivatives of any one of the aforementioned hypoglycaemic agents.

15

>

- 31. A method according to claim 5, wherein the physiologically active agent is selected from the group consisting of a steroid, hormone derivative, non-steroidal anti-inflammatory drug, opioid analgesic, antihistamine, antinauseant, antioestrogen, aromatase inhibitor, anxiolytic, prostaglandin, anti-viral drug, anti-migraine compound, antihypertensive agent, anti-malarial compound, bronchodilator anti-depressant, anti-Alzheimer's agent, neuroleptic and antipsychotic agent, anti-Parkinson's agent, antiandrogen and anorectic agent.
- 25 A method according to claim 5, wherein the physiologically active agent 32. is selected from the group consisting of testosterone, oestradiol, ethinyloestradiol, progesterone, norethisterone acetate, ketoprofen, flurbiprofen, naproxen, diclofenac, fentanyl, buprenorphine, alfentanil, sufentanil, codeine, dihydrocodeine, methadone, scopolamine, 30 metochlopramide, prochlorperazine, ondansetron, tamoxifen. epitiostanol, exemestane, 4-hydroxy-androstenedione and its derivatives, alprazolam, alprostadil, prostacylcin and its derivatives, melatonin, ndocosanol, tromantadine, lipophilic pro-drugs of acyclovir, low molecular weight heparin, enoxaparin, sumatriptan, amlodipine, nitrendipine,

primaquine, minoxidil, minoxidil pro-drugs, pilocarpine, salbutamol, terbutaline, salmeterol, ibogaine, bupropian, rolipram, tacrine, fluphenazine, haloperidol, N-0923, cyproterone acetate, fluoxetine, phentermine, perphenazine, chlorpromazine, morphine and mazindol.

- 33. A method according to claim 5 wherein the physiologically active agent is selected from the group consisting of buspirone, dextroamphetamine, phendimetrazine tartrate, sibutramine, lidocaine and ketamine.
- 10 34. A drug delivery system according to claim 5, wherein the system is applied to the mucosal membrane as a spray.
- 35. A drug delivery system according to claim 34 wherein the spray is delivered by an aerosol which is a fixed or variable metered dose
  aerosol.